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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

SAUNDERS, DAVID A

ART UNIT PAPER NUMBER

1644

DATE MAILED: 04/09/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

893,470

Applicant(s)

Smith et al

Examiner

SAUNDERS

Group Art Unit

1,644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 11/25/02
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 111; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 46-87 is/are pending in the application.
- Of the above claim(s) 70-87 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 46-69 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____.

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

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Claims 46-87 are pending.

Applicant's election with traverse of Group I (claims 46-65) in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the restriction requirement did not adequately explain the reasons for there being a search burden to search all Groups. This is not found persuasive because the search for the claimed culturing method of Group I is a sufficient burden for the examiner because the claims are broad and unfocused. The searches for the cells and their use in treatment even if these involve overlapping classes/subclasses, require searches for different features --i.e. cells with enhanced biological function per se and their uses. Nothing in applicant's disclosure has shown that the method of Group I uniquely provides cells with enhanced biological function. In fact, it is conventional to obtain cells with enhanced biological function by merely culturing cells in the presence of various growth/differentiation factors, irrespective of conditions of medium replacement. Therefore the search for cells and their use involves an added and undue search burden.

The requirement is still deemed proper and is therefore made FINAL.

Claims 46-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 46 and 56, in the second and last lines of each claim, the term "enhanced biological function" is indefinite. It is not clear what serves as the baseline biological function

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which would be considered as non-enhanced and against which one could make a comparison to determine that some function has been enhanced.

Specifically is the biological function “enhanced” in comparison to the function the cells would have had if left in vivo, as opposed to having been cultured ex vivo? Is “enhanced” function to be compared to the function of isolated cells which have cultured in some manner other than that claimed? Applicant should consider addressing by incorporating language from page 5, lines 11-15 and/or page 10, lines 1-2.

In claims 47 and 57, last line of each, “ability to function similar to naturally occurring tissue” is vague because the word “similar” is a relative term which is not defined in the claim or in the specification.

Claims 47, 55, 57 and 65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims contain new matter.

In claims 47 and 57 the term “ability to function similar to naturally occurring tissue” is overly broad in comparison to what can be properly supported in the original disclosure. It appears that applicant derived this language from page 11, lines 1-5, which states “ability to proliferate leading to development/regeneration of tissue similar to naturally occurring function.” Since applicant has not incorporated all limitations recited in the specification, he is improperly claiming something that encompasses more than what is supported.

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In claims 55 and 65 "non-myeloid-derived dendritic cells" is new matter. Page 9, line 4 has recited that dendritic cells can be "myeloid- or lymphoid derived". To now recite "non-myeloid" instead of "lymphoid" is to claim at something of greater scope than what is properly supported.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 46-47, 49, 55-57, 59 and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Romani et al. (JEM, 180, 83, 1994).

Romani et al. teach a method of culturing human dendritic cell precursors to form dendritic cells by culturing the cells

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with a medium supplemented with the stimulating factor GM-CSF and the cytokine TNF. Culture medium was exchanged "every other day by aspirating 0.3 ml medium and adding back 0.5 ml medium with cytokines (page 85, col. 1). Applicant's claims are of sufficient breadth, in light of the all encompassing disclosure, that what is taught by Romani et al. is sufficient to clearly anticipate instant claims 46, 49, 56 and 59.

Instant claims 47 and 57 are considered anticipated because the term "ability to function similar to naturally occurring tissue" encompasses any of the structural features noted by Romani et al. at page 85. Also the phenotypic and functional features noted by Romani et al. at pages 26-27 are consistent with these claims.

Claims 55 and 64 are anticipated since the cell population cultured was from blood, rather than bone marrow.

Claims 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Siena et al. (Exper. Hematol. 23, 1463, 1995).

Siena et al. teach a method of culturing human CD34+ cells to form dendritic cells by culturing the cells with a medium supplemented with various differentiation factors. Culture medium was replaced every 4-5 days. See page 1464, para.

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Spanning cols. 1-2. This is sufficient to anticipate instant claims 46, 49, 56 and 59.

Claims 47 and 57 are included since Siena et al. observed structural, phenotypic, and functional properties of the dendritic cells by culturing the cells with a medium supplemented with various differentiation factors. Culture medium was replaced every 4-5 days. See page 1464, para. Spanning cols. 1-2. This is sufficient to anticipate instant claims 46, 49, 56 and 59.

Claims 47 and 57 are included since Siena et al. Observed structural, phenotypic, and functional properties of the dendritic cells obtained (e.g. page 1464, col. 2).

Claims 55 and 64 are anticipated since blood was collected to obtain the cells (page 1464, col. 1).

Claims 46-47, 49, 53-57, 59, and 63-65 are rejected under 35 U.S.C. 102(e) as being anticipated by Steinman et al. (5,994,126).

Steinman et al. teach essentially the same as Romani et al., cited supra. See cols. 26 and 42, for example. Claims are rejected following a like rationale. In addition to the claims rejected over Romani et al., the following claims are rejected.

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Claims 54 and 64 are included because Steinman et al. teach both bone marrow and blood derived cells (col. 13, lines 3-9).

Claims 53 and 63 are rejected because the reference teaches antigen priming of the dendritic cells (e.g. col. 21, lines 29+).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

March 28, 2003

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182-1644